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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,573	07/11/2003	Babu J. Mavunkel	219002030100	3779
25225	7590	12/06/2005	EXAMINER	
MORRISON & FOERSTER LLP 12531 HIGH BLUFF DRIVE SUITE 100 SAN DIEGO, CA 92130-2040			PERLINGER, SARAH E	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 12/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/618,573	MAVUNKEL ET AL.	
	Examiner Sarah E. Perlinger	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 11 July 2003.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-11 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-11 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

1. Claims 1-11 are pending.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-10 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In conjunction with the lack of sufficient description, claims 8-10 fail to particularly point out variation of operable conditions and recipient compounds for amination to proceed. The scope that is enabled is limited to the “Amination of methyl indole-3-carboxylate” (Specification, Example 3).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The specification lacks sufficient description in the claimed scope when “a recipient compound” is aminated and “under conditions wherein said amination can proceed.” The specification merely describes “Amination of methyl indole-3-carboxylate” and lacks description of temperature conditions which apply to the method (Specification, Example 3). The

specification also lacks sufficient description in the claimed scope when “the recipient compound comprises indole.” The specification describes a method in which methyl indole-3-carboxylate is aminated (Specification, Example 3) however, does not describe amination of other indoles.

In the specification there is no delineation of the kind of structure or formula a recipient compound may include or exclude. Furthermore, the specification fails to delineate “conditions under which said amination can proceed.” It is noted in the art that broadly such description encompassed such structures and conditions such as found in US 6,248,925 (column 5) and US 5,589,596 (Example 1) for which no description or starting material for such structure was disclosed but read on by the claims. Recipient compounds and conditions under which amination can proceed and their description are particularly pertinent at the point of novelty over the art. Absent sources, the public is offered mere language rather than enablement. In re Howarth 210 USPQ 689. The claims embraced recipient compounds and conditions of US 6,248,925 and US 5,589,596, however the description seen in the specification is limited to those found on pages 3 and 5. It is recommended that the particular recipient compound and conditions under which amination can proceed be explicitly delineated in the claims.

3.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2-4 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by the following references which disclose chemical compounds delineated by these claims.

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See US 4,472,194 (column 1, lines 45-47) and US 4,801,717 (column 3, line 59).

4. ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Assche et al. US 4,472,194 or Tessier et al. US 4,801,717 .

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Assche et al. US 4,472,194 or Tessier et al. US 4,801,717 .

Determination of the scope and content of the prior art (MPEP§ 2141.01)

US 4,472,194 and US 4,801,717 disclosed anticipatory compounds against the base claim as delineated.

Ascertainment of the difference between the prior art and the claims (MPEP § 2141.02)

The difference between the species claim 7 and the anticipated compounds (US 4,472,194, column 1, lines 46-47) is that instead of the base structure having only one trifluoromethyl substituent, the instant claimed species differ from the prior art compounds by one additional trifluoromethyl substituent in the ortho position on the base compound. US 4,801,717 discloses the base compound substituted “with at least one” trifluoromethyl substituent (US 4,801,717 columns 1 and 2) occupying any position on the ring.

Finding of prima facie obviousness-rationale and motivation (MPEP § 2142-2143)

One having ordinary skill in the art would be in possession of such modification with one trifluoromethyl aryl substitution because both prior art references are of analogous art and thus such modification has been clearly guided to one skilled in the art. US 4,801,717 is analogous

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art to US 4,472,194 due to the fact that US 4,472,194 discloses a compound with the same base structure as seen in US 4,801,717 (see US 4,472,194 column 1, and US 4,801,717, column 4). Furthermore, US 4,801,717 discloses the same optional substituents for the common compound (see columns 1 and 2) as disclosed in US 4,472,194 (see column 1) and the compounds disclosed in both arts are used for the purpose of increasing the growth of vegetables (see US 4,801,717 column 1, US 4,472,194 column 1 and MPEP § 2141.01). One having ordinary skill in the art would be motivated to make such modification knowing that reasonable success has been demonstrated in analogous compounds (US 4,801,717, columns 4 and 5). It is *prima facie* obvious to modify one known compound with *attributes* proven in analogous compounds.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Van Assche et al. US 4,472,194 or Tessier et al. US 4,801,717 .

Determination of the scope and content of the prior art (MPEP§ 2141.01)

US 4,472,194 and US 4,801,717 also disclosed methods of synthesis for the anticipatory products.

Ascertainment of the difference between the prior art and the claims (MPEP § 2141.02)

The difference between the method claim 11 and the anticipated method (US 4,472,194, columns 1 and 2) is that instead of using a hydroxylamine hydrochloric salt to obtain the compound of claim 1, the instant claimed method differs from the prior art method by using an N-protected hydroxylamine to obtain the compound of claim 1. US 4,801,717 (Example 1) generically discloses the process of making claim 1 compounds, beginning with a fluoro precursor to obtain a hydroxylamine.

Finding of *prima facie* obviousness-rationale and motivation (MPEP § 2142-2143)

One having ordinary skill in the art would be in possession of such modification of utilizing an N-protected hydroxylamine in the synthesis of the hydroxylamine compounds of claim 1 **because** the inclusion of an N-protective step in an operable analogous synthetic process is conventional and routine to the chemical art because N-protecting enhances specificity of functional sites. US 4,801,717 is analogous art to US 4,472,194 due to the fact that US 4,472,194 discloses a method of synthesizing the same base compound as seen in US 4,801,717 (see US 4,472,194 columns 1 and 2, and US 4,801,717, Example 1). One having ordinary skill in the art would be motivated to make such modification knowing that reasonable success has been demonstrated in analogous methods. It is *prima facie* obvious to modify one known method with *attributes* proven in analogous methods.

5. ***Conclusion***

None of the claims are allowable.

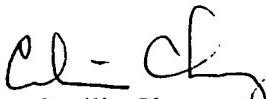
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Sarah E. Perlinger, whose telephone number is (571) 272-5574. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Cecilia Tsang, can be reached at (571) 272-0562. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

11/28/2005



Cecilia Chang  
Primary Examiner  
Art Unit 1625